JUN 11 2010

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K101127

Sponsor:	**Contec Medical Systems Co., Ltd** No. 24, West Huanghe Road Qinhuangdao, Hebei, 066000, China Establishment Registration Number: 3006979678 Contact Person: Mr. Li Xueyong, Quality Manager Tel:+86-335-8015490 Fax: +86-335-8015505 Email: lxyong1011@163.com
Correspondent:	Ms. Diana Hong Mr. Tarzan. Wang Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No. 19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: (240)238-7587 Email: Diana.hong@mid-link.net
Proposed Device Information	
Trade Name	Patient Monitor;
Model:	PM50;
Classification Name:	monitor, physiological, patient;
Product Code:	MWI;
Subsequent Product Codes:	DQA,DXN
Regulation Number:	870.2300;
Device Class:	II
Intended Use:	The patient monitor is a portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial haemoglobin (SpO_2), pulse rate(PR), Non-invasive measurement of blood pressure(NIBP) of adult

	patients in hospitals, medical facilities, and sub-acute environments. The patient monitor is intended for spot-checking and/or continuous monitoring of patients.
Predicate Device:	VS-800 Vital Signs Monitor K Number: K063055
Device Description:	The proposed device, PM50 Patient Monitor, is a portable device, which is intended for measuring and/or cont pulse oxygen saturation (SpO_2), pulse rate (PR), systolic pressure (SYS), diastolic pressure (DIA) and mean arterial pressure (MAP) on adult and pediatric.
Testing Conclusion:	Performance testing including clinical and laboratory testing was conducted to validate and verify that the proposed device, PM50 Patient Monitor met all design specifications and was substantially equivalent to the predicate device.
Clinical Test Discussion	The proposed device, PM50 Patient Monitor was tested in accordance Annex EE of ISO 9919 to evaluate SpO2 measurement accuracy. The test was sponsored by Contec Medical Systems Co., Ltd. and investigated in Qinhuangdao Maternal and Child Health Hospital. The proposed device, PM50 Patient Monitor was tested in accordance AAMI Sp10 to evaluate NIBP measurement accuracy. The test was sponsored by Contec Medical Systems Co., Ltd. and investigated in Qinhuangdao Maternal and Child Health Hospital. There are no any adverse effects and complications during test, the data obtained in the test meet the accuracy requirements of ISO 9919:2005 and ANSI/AAMI SP10:2002+A1: 2003+A2:2006.
SE Conclusion:	The proposed device, PM50 Patient Monitor is

substantially equivalent (SE) to the predicate device, VS-800 Vital Signs Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 11 2010

Contec Medical Systems Co., Ltd.
c/o Ms. Diana Hong
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 5D, No. 19, Lane 999, Zhongshan No. 2 Road (S)
Shanghai, 200030
CHINA

Re: K101127
Trade/Device Name: Patient Monitor, PM50
Regulatory Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MWI
Dated: April 15, 2010
Received: April 22, 2010

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

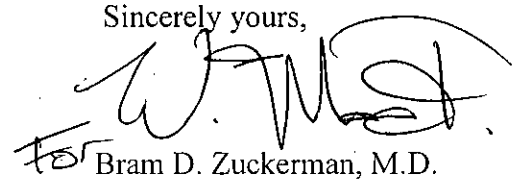
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): [redacted] K101127

Device Name: Patient Monitor, PM50

Indications for Use:

The Patient Monitor is a portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial haemoglobin (SpO_2), pulse rate(PR), Non-invasive measurement of blood pressure(NIBP) of adult patients in hospitals, medical facilities, and sub-acute environments. The patient monitor is intended for spot-checking and/or continuous monitoring of patients.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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